K132140

FEB - 4 2014

510(K) Summary

807.92(C)

Company Name: Duteck Industrial Co., Ltd

Company Address: 3F-2, No 26, Ln513 Rui-Kuang Rd
Taipei 114, Taiwan ROC

Telephone number: 886-2-8797-5035

Fax number : 886-2-2658-9280

Contact person: Joseph Chan

Summary preparation: June 11, 2013

Device name: 807.92(a)(2)

Trade name: Duteck(micHealth) Digital Clinical Thermometer, DT2306

Regulation Name: Digital Clinical Thermometer

Product Code: FLL

Registration Number: 9616844

Regulation Number: 21 CFR 880.2910

Regulatory Class: II

Predicate device: 807.92(a)(3)

Duteck Digital Clinical Thermometer (K992327)

Device description: 807.92(a)(4)

Duteck (micHealth) Digital Clinical Thermometer, DT2306 series is hand-held, reusable, battery operated device that can measure human body temperature via the human oral and armpit.

Device intended to use: 807.92(a)(5)

Duteck (micHealth) Digital Clinical Thermometer, DT2306 series is electronic thermometer using a thermopile detector to detect body temperature from the oral or armpit. It intended

for the intermittent measurement of human body temperature in people of all ages.

Comparison of technical characteristics: 807.92(a)(6)

ELEMENT OF COMPARISON	Duteck Digital Clinical Thermometer	Duteck (micHealth) Digital Clinical Thermometer, DT2306 series
510(K) Number	K992327	New
Displayed Temperature Range	32°C~42.0°C(89.6.0°F~109.2°F)	32.00°C~42.00°C(89.60°F~109.20°F)
Operation Environment	16°C~40°C(60.8°F~104°F)	16.00°C~40.00°C(60.80°F~104.00°F)
Power Requirement	LR41 1.5V batteries x1	CR 1620 3V x1
Display Resolution	±0.1°C/°F	±0.01°C/°F
Display	TN LCD	TN LCD
Response Time	15 second	4 second

Safety and effectiveness 807.92(b)

The Duteck (micHealth) Digital Clinical Thermometer, DT2306, had been tested to the appropriate electrical tested standard and biocompatibility standards have been found safe for intended use. (As Appendix III)

Conclusion: 807.92(b)(3)

The Duteck (micHealth) Digital Clinical Thermometer is as same as the predicate device in intended use and technological characteristics. After analyzing performance and safety testing, it is the conclusions of Duteck (micHealth) Digital Clinical Thermometer is as safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness.

Sincerely Yours,

Joseph Chen

Mr. Joseph Chen

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 4, 2014

Duteck Industrial Company, Limited
C/O Joseph Chen, President
3F-2, Number 26, Lane 513
Rui-Kuang Road
Taipei 114
Taiwan R.O.C.

Re: K132140
Trade/Device Name: Duteck (micHealth) Digital Clinical Thermometer, DT2306 series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 7, 2014
Received: January 15, 2014

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132140

Device Name
micHealth Digital Clinical Thermometer, DT2306 series

Indications for Use *(Describe)*

Duteck (micHealth) Digital Clinical Thermometer, DT2306 series (product code FLL) is used to measure human body temperature with the following features:

The device display body temperature in digital format at LCD
The device make intended contact with patient in 2 ways

(1) Surface contact: armpit.
(2) Invasive contact: oral.

The device is used and installed by patients, Nurses, doctors and people with the exception of handicapped people and children.

The device is used in ENVIRONMENT of room temperature and normal environment condition.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sajjad H. Syed -S

Digitally signed by Sajjad H. Syed -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed -S, 0.9.2342.19200300.100.1.1=2000601742
Date: 2014.01.30 14:55:10 -05'00'

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